#### **REMARKS**

Claims 155-170 are pending in the application. Claims 1-52 and 117-154 have been cancelled in prior Replies. Claims 53-116 have been withdrawn in a prior Reply. Claim 163 is currently amended. These claims have been cancelled, withdrawn, or amended without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file continuation applications directed to the subject matter of any claim cancelled for any reason.

The amendment to the pending claims is made to more clearly define the inventions. It is submitted that the amendment introduces no new matter and entry of the same is respectfully requested. By this amendment, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which the Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

### I. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 155-170 are rejected under 35 U.S.C. § 112, ¶ 1 for lack of written description. Office Action mailed 6 May 2004 at page 2. Applicants respectfully traverse.

The Examiner maintains that claims 155-170 contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *Id.* The Examiner states that "[t]he claims are directed to a composition free of chromium or free of added chromium" while "all the compositions disclosed in the specification comprise chromium." *Id.* citing pages 3, 10, and 11, and claims 1-116 of the specification. First, Applicants respectfully point out that the Examiner's rejection is inapplicable to claims 155-162 because they do not contain the limitation "free of added chromium." For this reason, the Examiner's rejection should be withdrawn with respect to claims 155-162.

Applicants respectfully submit that the rejection of claims 155-170 under 35 U.S.C. § 112, first paragraph is improper for two reasons. First, it is important to note that not all of the exemplary compositions disclosed in the specification comprise chromium. Instead, the specification clearly states that different embodiments of the invention *may* comprise chromium. See, for example, page 9, lines 9-11. The word "may" unambiguously demonstrates that the embodiments described in this manner may or may not include chromium. Thus, this language reasonably conveys to one skilled in the art that while

chromium *may* be included in embodiments of the invention, its presence is not required. Second, a claim that omits an element described in the specification should only support a rejection under 35 U.S.C. § 112, first paragraph if the applicant's disclosure makes it "crystal clear" that the element is "essential" or "critical" to the invention or that the variation contemplated in the claim is "outside the stated purpose of the invention." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 993, 50 U.S.P.Q.2d (BNA) 1607 (Fed. Cir. 1999), quoting *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d (BNA) 1498, 1503 (Fed. Cir. 1998); see also *In re Peters*, 723 F.2d 891, 221 U.S.P.Q. 952 (Fed. Cir. 1983) (claim omitting an element described in the specification was allowable because the specification did not describe the element as essential or critical). Here, not only have the Applicants not described chromium as an essential or critical element, but by using the permissive "may," the Applicants have not required its presence at all. Accordingly, for these reasons, Applicants respectfully submit that the rejection of claims 155-170 was improper and request that the Examiner reconsider and withdraw this rejection.

### II. REJECTIONS UNDER 35 U.S.C. § 103

## A. Rejection of Claims 155, 156, and 158-162 under 35 U.S.C. § 103(a) over Riley

Claims 155, 156, and 158-162 are rejected under 35 U.S.C. § 103(a). Office Action at page 3. Specifically, the Examiner asserts that these claims are "unpatentable over Riley (US 5,976,568)." *Id.* Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Applicants assert that the Examiner has failed to establish a *prima facie* case of obviousness because Riley fails to teach or suggest each and every element of the claimed invention. Specifically, Riley does not teach a composition comprising minerals consisting of selenium and zinc; and vitamins consisting of vitamin C, vitamin E, folic acid, biotin, pantothenic acid, niacin, pyridoxine, riboflavin, cyanocobalamin, and thiamine. Indeed, the Examiner even admits that "Riley does not teach expressly a composition consisting of the ingredients above." Office Action, page 3.

Accordingly, Applicants respectfully request that the present rejection of claims 155, 156, and 158-162 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

# B. Rejection of Claims 162, 164, and 166-170 under 35 U.S.C. § 103(a) over Riley in view of Wakat

Claims 162, 164, and 166-170 are rejected under 35 U.S.C. § 103(a). Office Action at page 4. Specifically, the Examiner asserts that these claims are "unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128)." *Id.* Applicants respectfully traverse.

Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully submit that the present rejection should be withdrawn because the Examiner's *prima facie* obviousness rejection is improper. As discussed above, Riley fails to teach each and very element of the claimed invention. Wakat fails to remedy the deficiencies of Riley as it fails, either singly or in combination, to teach or suggest each and every element of the claimed compositions.

Furthermore, there is no teaching, suggestion or motivation that can be derived from the references of record to combine the alleged teachings of the references. For example, the Examiner alleges that Riley teaches a "supplemental nutrient oral daily dosage composition comprising . . . about 50 to about 800 mcg of foliate." *Id.* The Examiner further alleges Wakat teaches that "for supplemental purpose, folic acid may be employed in the range of 0.35 mg to 10 mg," concluding that "it would have been prima facie obvious . . . to employ the amount of folic acid herein in an oral dosage form." *Id.* Applicants assert that the Examiner has failed to show the requisite teaching, suggestion or motivation in the references of record to combine the alleged teachings of Riley and the alleged teachings of Wakat to produce the compositions defined by any one of claims 162, 164, and 166-170. Therefore, Applicants assert that the Examiner's rejection based upon a *prima facie* case of obviousness

is improper. In re Rouffet, 149 F.3d 1350,1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998)(stating that if the combination of references teach every element of the claimed invention without a motivation to combine, then a rejection based upon a prima facie case of obviousness is improper)(emphasis added).

Accordingly, Applicants respectfully request that the present rejection of claims 162, 164 and 166-170 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

### C. Rejection of Claims 157 and 165 under 35 U.S.C. § 103(a) over Riley in view of Wakat and in further view of Anderson

Claims 157 and 165 are rejected under 35 U.S.C. § 103(a). Office Action at page 5. Specifically, the Examiner asserts that these claims are "unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of Anderson (US 5,278,329)." *Id.* Applicants respectfully traverse.

Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully submit that the present rejection should be withdrawn because the Examiner's *prima facie* obviousness rejection is improper. As discussed above, Applicants assert that (1) Riley and Wakat, singly or in combination, fail to teach each and every element of the claimed invention, and (2) there is no teaching, suggestion or motivation that can be derived from Riley and/or Wakat to combine the teachings of the references. Anderson fails to remedy these deficiencies. Therefore, Applicants respectfully request that the present rejection of claims 157 and 165 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

### **CONCLUSION**

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. In addition, filed concurrently herewith is a request for Examiner's interview.

If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

5 August 2004

Reg. No. 33,754

Preston Gates Ellis & Rouvelas Meeds, LLP 1735 New York Avenue NW, Suite 500 Washington, DC 20006

Telephone: (202) 628-1700 Facsimile: (202) 331-1024